



**ReSound® Personal Hearing System BT2-ES, BT2-EV, and BT241**

**SUMMARY OF SAFETY AND EFFECTIVENESS**

Substantial equivalence for the ReSound® Personal Hearing Systems BT2-ES, BT2-EV, and BT241 to the predicate device, the ReSound® Personal Hearing System BT2-C, (marketed as the BT2-E Encore), 510(k) No. K943788, September 21, 1994, is based on the following:

- These air-conduction hearing instruments, intended to amplify and transmit sound to the ear, are designed for hearing losses from mild to moderately-severe.
- These devices are powered by a standard hearing aid battery (type 13).
- These devices are manufactured and delivered completely assembled to the hearing aid dispenser using materials and techniques widely used by other manufacturers of hearing devices.
- The intended use, performance specifications, functions and operations of the ReSound® Personal Hearing Systems BT2-ES, BT2-EV, and BT241 are substantially equivalent to that described in the 510(k) Premarket Notification for the ReSound® Personal Hearing System BT2-E.
- The ability to program digitally the fitting parameters of the hearing devices and the ability of the devices to retain one program, even when the main battery is removed and changed, is the same as in the ReSound® Personal Hearing System BT2-E. The BT2-ES and BT2-EV are dispenser programmable, whereas the BT241 programming is factory preset and may be reprogrammed at the factory only.